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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/194,619	08/25/2003	Howard Kenneth	P-1018	3413
7590 07/21/2005			EXAMINER	
Howard K. Shapiro 214 Price Avenue Apt . F-32 Narberth, PA 19072			KOLKER, DANIEL E	
			ART UNIT	PAPER NUMBER
			1649	
DATE MAILED: 07/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/194,619

Applicant(s)

KENNETH, HOWARD

Examiner

Daniel Kolker

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/16/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1 - 8, drawn to methods of selecting a drug candidate agent, wherein an indicator system is used which is capable of detecting stress protein expression, and fibroblasts are obtained from patients that are known to have and not to have a predetermined neurological disease.

Group 2, claim(s) 9 - 10, drawn to tissue culture systems.

Group 3, claim(s) 11 - 25, drawn to methods of determining the presence of a predetermined neurodegenerative disease.

Group 4, claim(s) 26, drawn to a method useful for experimental screening of candidate drug agents wherein mammalian fibroblasts are obtained from a donor having a neurodegenerative disorder, and wherein suppression of a disease-related protein is detected.

Group 5, claim(s) 27, drawn to a composition consisting of mammalian fibroblasts.

2. The inventions listed as Groups 1 - 5 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: PCT Rule 13.2 states: "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." The first stated technical feature, a screening method based on concomitant cultures of fibroblasts from a patient with a neurological disease and a from a control patient under specific conditions, is

Art Unit: 1649

not a contribution over the prior art and therefore does not constitute a special technical feature as defined in PCT Rule 13.2.

May et al. (1985. Journal of the Neurological Sciences 70:101-112) teach concomitant culture of fibroblasts from patients with Huntington's disease and from control patients. The specific cell lines and culture conditions are detailed in the first paragraph of p. 103. May et al. teach growth of these cultures in the absence of any candidate agents, which correspond to claim 1, parts (a) and (b) and claim 1(c)(1) and 1(c)(2). They also teach culture of the cells in the presence of a drug candidate agent, namely the antioxidant propyl gallate (see p. 108, first complete paragraph). This corresponds to claim 1(c)(3) and 1(c)(4). Furthermore they tested the control culture in the presence of a chemical stress protein-inducing parameter with and without the agent. The chemical stress protein-inducing parameter was 15mM L-HCA (see p. 108, first complete paragraph). This corresponds to claim 1(c)(5) and 1(c)(6). Finally, May et al. used an indicator system capable of detecting stress protein expression. The indicator system was the percentage of cells which are viable; since cells die upon sufficient levels of stress protein the viability assay corresponds to claim 1(d) as viability tests fairly anticipate use of an indicator system. The examiner notes that the limitations directed to the agent are non-limiting to the "use" recitation in claim 1(d). Further the examiner notes that the first technical feature is a cell culture of fibroblast cells from a patient having a pre-determined neurological disease. Since May fairly teaches cultures of fibroblasts from patients known to have Huntington's disease the first technical feature is not a contribution over the prior art and therefore the claims lack unity.

Because the first claimed technical feature is not a contribution over the prior art, there is not a special technical feature which links all inventions.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

July 18, 2005

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER

7-18-05